



PTO-8A (08-00)

Approved for use through 10/31/2002, OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 7

Application Number

09/966,493

Filing Date

September 28, 2001

First Named Inventor

Joseph R. Luber

Group Art Unit

1615

Examiner Name

Robert Joynes

Attorney Docket Number

MCP-274

U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear |
|-------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| S.T. | | 582,438 | | J. Scheidler | 05-11-1897 | |
| | | 599,865 | | E.L. Richards | 03-01-1898 | |
| | | 2,307,371 | | H.B. Hileman | 01-05-1943 | |
| | | 2,996,431 | | R.H. Barry | 08-15-1961 | |
| | | 3,085,942 | | Louis Magid et al. | 04-16-1963 | |
| | | 3,146,169 | | D. Stephenson et al. | 08-25-1964 | |
| | | 3,627,583 | | John P. Troy et al. | 12-14-1971 | |
| | | 3,726,622 | | Georges D. DeTroyer et al. | 04-10-1973 | |
| | | 3,804,570 | | Gunter Hoschele et al. | 04-16-1974 | |
| | | 3,832,252 | | T. Higuchi et al. | 08-27-1974 | |
| | | 4,139,589 | | Monique Beringer et al. | 02-13-1979 | |
| | | 4,230,693 | | Henry J. Izzo et al. | 10-28-1980 | |
| | | 4,271,206 | | Harry F. Fariel et al. | 06-02-1981 | |
| | | 4,273,793 | | Harry F. Fariel et al. | 06-16-1981 | |
| | | 4,292,017 | | Wallace A. Doepel | 09-29-1981 | |
| | | 4,362,757 | | Andy C. Chen et al. | 12-07-1982 | |
| | | 4,372,942 | | Paul A. Cimiluca | 02-08-1983 | |
| | | 4,392,493 | | Halbe J. Niemeijer | 07-12-1983 | |
| | | 4,425,332 | | Michael H. James | 01-10-1984 | |
| | | 4,473,526 | | Eugen Buhler et al. | 09-25-1984 | |
| | | 4,518,335 | | Vimal K. Pujari | 05-21-1985 | |
| | | 4,528,335 | | Larry M. Selby et al. | 07-09-1985 | |
| | | 4,533,345 | | John A. Louw | 08-06-1985 | |
| | | 4,544,345 | | Eugen Buhler et al. | 10-01-1985 | |
| S.T. | | 4,569,650 | | Hans Kramer | 02-11-1986 | |

| | | | |
|--------------------|------|-----------------|----------|
| Examiner Signature | S.T. | Date Considered | 10/20/04 |
|--------------------|------|-----------------|----------|



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 7

Application Number 09/966,493

Filing Date September 28, 2001
First Named Inventor Joseph R. Luber
Group Art Unit 1615
Examiner Name Robert Joynes
Attorney Docket Number MCP-274

U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear |
|-------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| S.T | | 4,749,575 | | Avner Rotman | 06-07-1988 | |
| | | 4,762,719 | | Mark Forester | 08-09-1988 | |
| | | 4,781,714 | | J.B. Eckenhoff et al. | 11-01-1988 | |
| | | 4,813,818 | | Michael Sanzone | 03-21-1989 | |
| | | 4,820,524 | | Norbert I. Berta | 04-11-1989 | |
| | | 4,929,446 | | Raymond A. Bartolucci | 05-29-1990 | |
| | | 4,965,027 | | Nobuyuki Takahashi | 10-23-1990 | |
| | | 4,980,169 | | Alfred Oppenheimer et al. | 12-25-1990 | |
| | | 5,002,970 | | George A. Eby, III | 03-26-1991 | |
| | | 5,059,112 | | Marianne Wieser | 10-22-1991 | |
| | | 5,089,270 | | Douglas B. Hampton et al. | 02-18-1992 | |
| | | 5,145,868 | | Andreas von Sprecher et al. | 09-08-1992 | |
| | | 5,146,730 | | Hani Sadek et al. | 09-15-1992 | |
| | | 5,188,840 | | Yoshimitsu Iida et al. | 02-23-1993 | |
| | | 5,200,191 | | Don Steele et al. | 04-06-1993 | |
| | | 5,213,738 | | Douglas B. Hampton et al. | 05-25-1993 | |
| | | 5,213,808 | | Daniel Bar-Shalom et al. | 05-25-1993 | |
| | | 5,228,916 | | Norbert I. Berta | 07-20-1993 | |
| | | 5,229,164 | | Heinrich Pins et al. | 07-20-1993 | |
| | | 5,368,863 | | James B. Eckenhoff et al. | 11-29-1994 | |
| | | 5,391,378 | | Richard Sanderson | 02-21-1995 | |
| | | 5,405,642 | | Paul M. V. Gilis et al. | 04-11-1995 | |
| | | 5,415,868 | | Floyd S. Smith et al. | 05-16-1995 | |
| S.T | | 5,436,026 | | Norbert I. Berta | 07-25-1995 | |

Examiner Signature

S.T

Date Considered

10/21/04



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 3 of 7

| | |
|-------------------------------|--------------------|
| Application Number | 09/966,493 |
| Filing Date | September 28, 2001 |
| First Named Inventor | Joseph R. Luber |
| Group Art Unit | 1615 |
| Examiner Name | Robert Joynes |
| Attorney Docket Number | MCP-274 |

U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear |
|-------------------|-----------------------|----------------------|-----------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| SJ | | 5,459,983 | | Hani Sadek et al. | 10-24-1995 | |
| | | 5,464,631 | | Charles E. Hoover et al. | 11-07-1995 | |
| | | 5,511,361 | | Erich W. Sauter | 04-30-1996 | |
| | | 5,538,125 | | Norbert I. Berta | 07-23-1996 | |
| | | 5,578,336 | | Woodrow C. Monte | 11-26-1996 | |
| | | 5,609,010 | | Erich W. Sauter | 03-11-1997 | |
| | | 5,614,207 | | Manoj N. Shah et al. | 03-25-1997 | |
| | | 5,679,406 | | Norbert I. Berta | 10-21-1997 | |
| | | 5,681,584 | | Louis Savastano et al. | 10-28-1997 | |
| | | 5,711,961 | | Alberto Reiner et al. | 01-27-1998 | |
| | | 5,795,588 | | Erich W. Sauter | 08-18-1998 | |
| | | 5,807,579 | | Zalman Vilkov et al. | 09-15-1998 | |
| | | 5,824,338 | | Richard L. Jacobs et al. | 10-20-1998 | |
| | | 5,827,874 | A | Meyer et al. | 10-27-1998 | |
| | | 5,830,501 | | Liang C. Dong et al. | 11-03-1998 | |
| | | 5,830,502 | | Liang C. Dong et al. | 11-03-1998 | |
| | | 5,834,035 | | Michio Osada et al. | 11-10-1998 | |
| | | 5,837,301 | | Robin A. Arnott et al. | 11-17-1998 | |
| | | 5,853,760 | A | LTS Lohmann Therapie-Systeme GmbH & Co. KG | 12-29-1998 | |
| | | 5,871,781 | | Garry L. Myers et al. | 02-16-1999 | |
| | | 5,942,034 | | Jeffrey D. Brehant et al. | 08-24-1999 | |
| | | 5,997,905 | | Daniel McTeigue et al. | 12-07-1999 | |
| | | 6,001,391 | A | Zeidler et al. | 12-14-1999 | |
| | | 6,103,257 | | Keith Nisonoff | 08-15-2000 | |
| SJ | | 6,117,479 | | John E. Hogan et al. | 09-12-2000 | |

| | | | |
|--------------------|----|-----------------|----------|
| Examiner Signature | SJ | Date Considered | 10/21/04 |
|--------------------|----|-----------------|----------|

JUN 28 2004

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 4 of 7

| | |
|------------------------|--------------------|
| Application Number | 09/966,493 |
| Filing Date | September 28, 2001 |
| First Named Inventor | Joseph R. Luber |
| Group Art Unit | 1615 |
| Examiner Name | Robert Joynes |
| Attorney Docket Number | MCP-274 |

U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear |
|-------------------|-----------------------|----------------------|--------------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| S.T | | 6,120,802 | A | Breitenbach et al. | 09-19-2000 | |
| | | 6,149,939 | | Matthew A. Strumor et al. | 11-21-2000 | |
| | | 6,149,943 | | Daniel McTeigue et al. | 11-21-2000 | |
| | | 6,200,590 | | John G. Eley | 03-13-2001 | |
| | | 6,248,760 | | Paul C. Wilhelmsen | 06-19-2001 | |
| | | 6,350,398 | | Jorg Breitenbach et al. | 02-26-2002 | |
| | | 6,365,185 | | Wolfgang A. Ritschel | 04-02-2002 | |
| | | 6,433,015 | B1 | Meyer | 08-13-2002 | |
| | | 6,727,213 | B2 | Waschenbach et al. | 04-27-2004 | |
| | | 6,730,646 | B1 | Waschenbach et al. | 05-04-2004 | |
| | | 2001/0001280 | A1 | Liang-Chang Dong et al. | 05-17-2001 | |
| | | 2002/0028240 | A1 | Toyohiro Sawada et al. | 03-07-2002 | |
| S.T | | 2003/0203016 | A1 | Dr. Suwelack Skin & Health Care AG | 10-30-2003 | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear | T ⁶ |
|-------------------|-----------------------|-------------------------|---------------------|-----------------------|---|--|---|----------------|
| | | Office ³ | Number ⁴ | KindCode ⁵ | | | | |
| S.T | | DE | 19954420 | A1 | LTS Lohmann Therapie-Systeme AG | 05-31-2001 | NOTE: English language abstract only | |
| S.T | | EP | 0 088 556 | B1 | Sumitomo Chemical Company Ltd. | 09-14-1983 | | |
| S.T | | EP | 0 239 983 | B1 | Boehringer Ingelheim International GmbH | 10-07-1987 | NOTE: English language abstract only | |

| | | | |
|--------------------|-----|-----------------|----------|
| Examiner Signature | S.T | Date Considered | 10/21/04 |
|--------------------|-----|-----------------|----------|



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 5 of 7

| | |
|-------------------------------|--------------------|
| <i>Application Number</i> | 09/966,493 |
| <i>Filing Date</i> | September 28, 2001 |
| <i>First Named Inventor</i> | Joseph R. Luber |
| <i>Group Art Unit</i> | 1615 |
| <i>Examiner Name</i> | Robert Joynes |
| <i>Attorney Docket Number</i> | MCP-274 |

FOREIGN PATENT DOCUMENTS

| Examiner Initials | Cite No. ¹ | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document mm-dd-yyyy | Pages, Columns, Lines, where relevant passages or relevant figures appear | T ⁶ |
|-------------------|-----------------------|-------------------------|---------------------|-----------------------|---|---|---|----------------|
| | | Office ³ | Number ⁴ | KindCode ⁵ | | | | |
| <i>S</i> | | EP | 0 294 993 | B1 | Pfizer Inc. | 12-14-1988 | | |
| | | EP | 0 387 885 | B1 | Bristol-Myers Squibb Company | 09-19-1990 | | |
| | | EP | 0 455 599 | A1 | Warner-Lambert Company | 11-06-1991 | | |
| | | EP | 0 481 547 | A1 | Unilever PLC & Unilever NV | 04-22-1992 | | |
| | | EP | 0 531 524 | B1 | SS Pharmaceutical Co. Ltd. | 03-17-1993 | | |
| | | EP | 0 572 731 | A1 | The Procter & Gamble Company | 12-08-1993 | | |
| | | EP | 0 619 854 | B1 | V. Kann Rasmussen Industri A/S | 03-04-1998 | | |
| | | EP | 0 646 650 | A2 | Fuisz Technologies Ltd. | 04-05-1995 | | |
| | | EP | 0 646 650 | A3 | Fuisz Technologies Ltd. | 03-27-1996 | | |
| | | EP | 0 788 790 | B1 | Jagotec AG | 05-19-2004 | | |
| | | EP | 0 834 516 | B1 | Kabushiki Kaisha Hayashibara Seibutsu Kagaku Kenkyujo | 04-08-1998 | | |
| | | EP | 0 861 659 | A1 | University of Kentucky Research Foundation | 09-02-1998 | | |
| | | EP | 0 950 402 | B1 | McNeil-PPC, Inc. | 05-14-2003 | | |
| | | EP | 1 077 065 | A1 | Chugai Seiyaku Kabushiki Kaisha | 02-21-2001 | | |
| | | GB | 866 681 | | May & Baker Ltd. | 04-26-1961 | | |
| | | GB | 888 038 | | The Wander Company | 01-24-1962 | | |
| | | GB | 936 386 | | The Wellcome Foundation Limited | 09-11-1963 | | |
| | | GB | 994 742 | | The Wellcome Foundation Limited | 06-10-1965 | | |
| | | GB | 1 144 915 | | Armour Pharmaceutical Company | 03-12-1969 | | |
| | | GB | 1 372 040 | | Boehringer Ingelheim | 10-30-1974 | | |
| | | GB | 1 464 388 | | Schering Aktien-Gesellschaft | 02-09-1977 | | |
| | | GB | 1 510 772 | | ACO Lakemedel AB | | | |
| <i>S</i> | | GB | 2 182 559 | A | Alza Corporation | 05-20-1987 | | |

| | | | |
|--------------------|--------------|-----------------|-----------------|
| Examiner Signature | <i>S. T.</i> | Date Considered | <i>10/20/04</i> |
|--------------------|--------------|-----------------|-----------------|



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Do not collect fees for information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 6 of 7

| | |
|-------------------------------|--------------------|
| Application Number | 09/966,493 |
| Filing Date | September 28, 2001 |
| First Named Inventor | Joseph R. Luber |
| Group Art Unit | 1615 |
| Examiner Name | Robert Joynes |
| Attorney Docket Number | MCP-274 |

FOREIGN PATENT DOCUMENTS

| | | | |
|-----------------------|-----|--------------------|----------|
| Examiner Signature | SIT | Date Considered | 10/21/04 |
|-----------------------|-----|--------------------|----------|



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
to a collection of information unless it displays a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 7 of 7

| | |
|-------------------------------|--------------------|
| <u>Application Number</u> | 09/966,493 |
| <u>Filing Date</u> | September 28, 2001 |
| <u>First Named Inventor</u> | Joseph R. Luber |
| <u>Group Art Unit</u> | 1615 |
| <u>Examiner Name</u> | Robert Joynes |
| <u>Attorney Docket Number</u> | MCP-274 |

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

| | | | |
|-----------------------|------|--------------------|----------|
| Examiner Signature | S. T | Date Considered | 10/21/04 |
|-----------------------|------|--------------------|----------|

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Unique citation designation number. 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231.

DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.